REMARKS

The Present Invention

The present invention pertains to processes for transducing a cell with a DNA sequence.

The Pending Claims

Claims 1-4 are currently pending. Claims 5 and 6 have been cancelled, without prejudice, as being drawn to a non-elected invention. Applicants reserve the right to pursue the subject matter of claims 5-6 in a continuation or divisional application.

The Office Action

Claims 1-4 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,342,390 in view of Alexander et al. (U.S. Patent No. 5,604,090) or Carter et al. (U.S. Patent No. 6,165,781).

Discussion of the Double Patenting Rejection

The Office has rejected claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,342,390 ("the '390 patent") in view of Alexander et al. or Carter et al. Reconsideration of the rejection is respectfully requested in view of the following comments.

The Office alleges that the only difference between claims 9-11 of the '390 patent and the pending claims is that the claims of the '390 patent "do not claim the step of introducing the genetically engineered cells containing AAV constructs in[to] a mammal." (Office Action, page 3). Accordingly, the Office cites Alexander et al. and Carter et al. as allegedly teaching that the genetically engineered cells transduced with AAV vectors can be introduced or reintroduced into a mammal so as to produce a protein

of interest (Alexander et al., column 6 bridging column 7; Carter et al., column 13). (Office Action, page 4).

Assuming, *arguendo*, that the art discloses the steps recited in the pending claims, this fact, in and of itself, does not render the claims unpatentable absent some motivation in the prior art to practice the claimed combination. Neither claims 9-11 of the '390 patent, nor the secondary references (*i.e.*, Alexander et al. and Carter et al.), provide any motivation to combine their teachings to arrive at the claimed invention.

At best, both of Alexander et al. and Carter et al. describe the use of packaged virus carrying an AAV vector to transduce the expression of an exogenous protein in a cell, and reintroducing the cell into a mammal. (*See*, Alexander et al., col. 8, lines 6-12; and Carter et al., col. 8, line 45, to col. 9, line 12). Therefore, it is clear that both of Alexander et al. and Carter et al. contemplate providing the exogenous gene and rep protein in *cis*.

Claims 9-11 of the '390 patent relate to providing the exogenous gene and rep protein in *trans*. One of ordinary skill in the art would not be motivated to apply the disclosure of Alexander et al. or Carter et al. to claims 9-11 of the '390 patent. Simply, Alexander et al. and Carter et al. fail to provide any teaching or fair suggestion that their methods should be employed in situations other than where the exogenous gene and the rep protein are provided in *cis*. Thus, even assuming Alexander et al. or Carter et al. describes *ex vivo* techniques of providing an exogenous gene and rep protein, one of ordinary skill in the art would not be motivated to modify claims 9-11 of the '390 patent (*i.e.*, providing the exogenous gene and rep protein in *trans*) with the methodology taught by Alexander et al. or Carter et al. (*i.e.*, providing the exogenous gene and rep protein in *cis*).

Furthermore, Alexander et al. and Carter et al. teach away from the present invention. As previously discussed, Alexander et al. and Carter et al. both provide complete virus particles to a cell. The only viral protein provided to the cell in the claimed method is the rep protein. The claimed process helps avoid the dangers of the presence of additional viral proteins (and, in particular, viral proteins in *cis* as provided by Alexander et al. and Carter et al.), which are known and include, *e.g.*, significant host

immune responses to transfected cells that express viral proteins on their surfaces (Application, page 2, lines 23-25). Similarly, there is no persistent expression of rep protein, and thus, effects associated with rep expression, such as cytotoxic effects and repression of expression of the DNA sequence of interest, are minimized. Thus, Alexander et al. and Carter et al. teach away from, and are irrelevant to the patentability of, the claimed process.

In view of the foregoing, the pending claims cannot be said to be unpatentable over claims 9-11 of the '390 patent in view of Alexander et al. or Carter et al. As such, withdrawal of this rejection is respectfully requested.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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